

R E M A R K S

In the initial Restriction Requirement mailed April 20, 2006, the Examiner issued a 500-way restriction. Specifically, the Examiner restricted the claims into five main groups labeled I, II, III, IV, and V. For each of these main groups, the Examiner required further restriction: i) into one of five sub-groups labeled A, B, C, D, and E; ii) into one of five sub-groups labeled F, G, H, I, G; and iii) into one of 4 sub-groups labeled J, K, L, and M. The Applicants elected group I and rendered the remaining sub-group restrictions moots by canceling all of the dependent claims reciting the species in the sub-groups. In the Office Communication dated September 29, 2006, the Examiner reiterated the sub-group restriction, despite the fact that no claims were pending directed toward the sub-group species. As explained below, Applicants disagree with the Examiner's sub-group restriction and submit that it is not supported under the law.

I. There Is No Legal Basis For Restriction Based on Claims that are Not Present

The statutory basis that allows claims to be restricted is found in 35 U.S.C. 121. This section, however, only allows restriction of distinct inventions **that are claimed**. The text of 35 U.S.C. 121 is as follows:

If two or more independent and distinct inventions **are claimed** in one application, the Director may require the application to be restricted to one of the inventions. ...

The MPEP 808 repeats the requirement from 35 U.S.C. 121 that restriction requirements must be based on what is claimed:

MPEP 808 Reasons for Insisting Upon Restriction

Every requirement to restrict has two aspects: (A) the reasons (as distinguished from the mere statement of conclusion) why each invention *as claimed* is either independent or distinct from the other(s); and (B) the reasons why there would be a serious burden on the Examiner if restriction is not required ... (*emphasis in original*)

Notably, the text in part (A) of MPEP 808 puts the "as claimed" language in italics, making it clear that what is actually claimed cannot be ignored.

In this case, the Examiner has maintained the sub-group restrictions even though the claims containing the species identified by the Examiner have been cancelled. In effect, the Examiner is requiring restriction to various species disclosed in the specification. This action by the Examiner is not supported by the law. Indeed, the law forbids reading limitations into the claims from the specification. Instead, the Examiner is required, under 35 U.S.C. 121 (and

MPEP 808), to examine what is currently claimed. As such, Applicants respectfully request that the Examiner withdraw the sub-group restrictions and Examine the pending claims.

II. The Legal Support Cited by the Examiner Relates to Species Election, not a Group Election

The legal support cited by the Examiner for maintaining the sub-group restrictions in the Office Communication relates to *species elections*, and not to group elections, and therefore does not support maintaining the sub-group restriction even if the claims had not been cancelled. In particular, in the Office Communication, the Examiner cites MPEP Form Paragraph 8.02 entitled "Election of Species; No Species Claim Present," quoting the following passage from this section: "Applicant is required under 35 U.S.C. 121 to elect a single disclosed **species**, even though this requirement is traversed." Applicants submit that the cited form paragraph does not provide legal grounds for restricting the claims into three sub-groups. The form paragraph cited by the Examiner (under MPEP 809.02(a) "Election of Species Required") relates to *species elections*, not to a group restriction as in the present case. Therefore, even if the claims containing the various species had not been cancelled, the legal support cited by the Examiner would only authorize issuing a species election.

III. The Examiner's 500-Way Restriction is Overly Burdensome

Even if the claims had not been cancelled and even if there was proper support for the ability to restrict the claims, the restriction is still improper as being overly burdensome. By requiring restriction into 5 main groups, 5 sub-groups, 5 additional sub-groups, and 4 additional sub-groups, the Examiner has issued a 500-way restriction as $5 \times 5 \times 5 \times 4 = 500$. Prosecuting 500 different applications would be unduly expensive and time consuming. Applicants submit that a 500-way restriction requirement is overly burdensome, and not what was intended by Congress under 35 U.S.C. 121 or by the founding father in drafting the patent clause in the U.S. Constitution.¹ This is not a case where 500 different, unrelated nucleic acid sequences are being claimed which might potentially justify a 500-way restriction. Instead, the originally filed

¹ "The Congress shall have Power... To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries;"
- U.S. Constitution, Article 1, Section 8, Clause 8

claims, as noted by the Examiner, were directed to five different inventions, including three general methods, one general kit, and one general composition.

In Applicants' initial Response to the Examiner's 500-way restriction, Group I was elected without traverse. Group I, which is directed toward general methods of making a transcription product with an RNA polymerase, was elected by canceling all pending claims and presenting new Claims 172-205 which are all within Group I. By canceling all of the pending claims, which included all of the dependent claims that initially triggered sub-group A-E (various N4 RNA polymerase deletion mutants), sub-group F-G (various N4 promoters), and sub-group J-M (various RNA polymerases) Applicants believed that restriction to all of these sub-groups was moot. Applicants also believed that this signaled their desire to have the general methods in Group I examined by the Patent Office, rather than a more specific embodiment described in dependent claims.

Applicants respectfully request that the Examiner reconsider the 500-way restriction and instead only require the 5-way restriction which Applicants have not traversed. A 5-way restriction would be keeping with the historical practices of the U.S. Patent Office, which has routinely examined general method claims along the line of those presented here.

IV. The Examiner's Initial Sub-Group Restriction Was Not Proper

Applicants respectfully submit that even if the Examiner's initial sub-group restrictions were considered a species election, such a species restriction is not proper and is hereby traversed. In particular, Applicants submit that the requirements under MPEP 808 have not been met as the Examiner has not explained: 1) why each invention as claimed is independent or distinct from the others and 2) the reasons why there would be a serious burden on the Examiner if the restriction were not required.

A. No Explanation of Why Species Independent and Distinct

The first requirement under MPEP 808 for insisting upon a restriction is "(A) the reasons (as distinguished from the mere statement or conclusion) why each invention as claimed is either independent or distinct from the others." In the initial Restriction Requirement, the Examiner grouped all three sub-groups (calling it collectively "A-M") and provides the following reasons for alleging independence of all 14 species in the sub-groups:

"In the instant case the different inventions, represent structurally different polypeptides and the polynucleotides encoding them. Therefore, where structural identity is required, such as for hybridization or expression, the different sequences have different effects." (Office Action, page 5).

The Examiner's rationale, however, fails to look at "each invention as claimed," as required under MPEP 808. The Applicants are claiming **methods** that employs an *RNA polymerase* and a *promoter* that binds the RNA polymerase - Applicants are not claiming **compositions** comprising the 14 species in the 3 sub-groups. Therefore, the fact that all of the species are physically different is irrelevant to these method claims.

Part of the Examiner's rationale is that the 14 different species "have different effects." However, 9 of the recited species are RNA polymerases (5 are deletion mutants of N4 RNA polymerase, 1 is an E. coli RNA polymerase, 1 is a T7 RNA polymerase, 1 is a T3 RNA polymerase, and 1 is a SP6 RNA polymerase), which, *in the context of the method claims*, all have the same "effect" (i.e. all 9 are cited as RNA polymerases). Likewise, 5 of the recited species are promoters (all 5 are N4 RNA polymerase promoters), and *in the context of the method claims*, all have the same "effect" (i.e., they all bind the RNA polymerase). As such, the Examiner's rationale fails in the context of the claimed general method claims. Therefore, the first prong of MPEP 808 has not been met by the Examiner, making the sub-group restriction improper under the law.

B. No Search Burden Exists

The second requirement under MPEP 808 for insisting upon a restriction is "(B) the reasons why there would be a serious burden on the examiner if restriction is not required." Under MPEP 808.02 the Examiner can show a serious burden by showing one of the following: (a) separate classification, (b) a separate status in the art when they are classifiable together; or (c) a different field of search. In this case, the Examiner recites a conclusory statement (relying on the faulty distinctiveness logic discussed above) without attempting to explain *why* there would be a serious burden if the 500-way restriction were not imposed:

"Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the literature and sequence searches required for each of the Groups are not required for another of the Groups, restriction for examination purposes as indicated is proper." (Office Action, page 6).

This collection of "reasons" is simply conclusory and therefore not sufficient. The Examiner never discusses how or why any of the species have a separate status in the art, nor does he point to any evidence. The Examiner never discusses the classification of any of the species, so he is unable to state that they are different. Finally, the Examiner never discusses how or why the search for one species is different from the other species, nor does he provide evidence. As the Examiner has failed to provide any evidence, as required, to show that a search burden exists, the second prong of 808 is not met. This is a second and independent reason that the Examiner's sub-group restriction is improper and should be withdrawn.

While the Examiner has not discussed any of the species classification, status in the art, or field of search, Applicants note that when such parameters are examined it is seen that there is no search burden. First, as noted above, 9 of the 14 species are RNA polymerases. The Examiner never alleges that the different RNA polymerases would have a different classification in the art or different status in the art, let alone provide *evidence* supporting such an assertion. Applicants submit that the RNA polymerase would not have a different classification or field of search, and certainly not in the context of a general method claim that only requires an "RNA polymerase." The same logic applies to the promoter sequences. The Examiner has not provided any discussion or evidence regarding these species as required for a lawful restriction. Again, the 5 recited promoter sequences are all N4 RNA promoter sequences, making it illogical for the Examiner to assert that these promoters would have a separate classification or require a different field of search, particularly in the context of a general method claim that only requires a "promoter sequence that binds the RNA polymerase."

As the Examiner has failed to provide reasons (rather than mere unsupported conclusions) regarding search burden, it is clear that no search burden exists. Therefore, Applicants submit that the sub-group restriction requirement was not proper and should be withdrawn by the Examiner.

V. Provisional Election

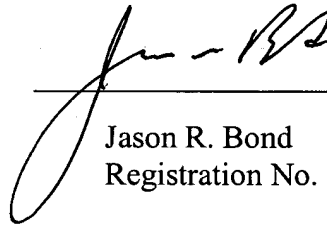
While Applicants believe that there is no legal basis for the Examiner maintaining the sub-group restriction, Applicants provide an election to 1 of the 500 groups offered by the Examiner only because this is required under 35 U.S.C. 121 to maintain the right to petition, and

as necessary, Appeal any final holding of restriction. The Applicants elect, with traverse, A from sub-group A-E; F from sub-group F-G, and K from sub-group J-M.

Conclusion

The reasons discussed above, Applicants respectfully request that the sub-group restriction be withdrawn. If the Examiner wishes to discuss this case, Applicants encourage the Examiner to call the undersigned at 608-218-6900 at the Examiner's convenience.

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